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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/828,498	04/05/2001	Jinhua Xiang	IOWA:030US/GNS	6829

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EXAMINER
WINKLER, ULRIKE

ART UNIT	PAPER NUMBER
1648	

DATE MAILED: 06/17/2003

13

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application N .	Applicant(s)	
	09/828,498	XIANG ET AL.	
	Examiner	Art Unit	
	Ulrike Winkler	1648	

-- The MAILING DATE of this communication appears n the cover sheet with the c rrespondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 February 2003* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-62* is/are pending in the application.

4a) Of the above claim(s) *12-62* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4 and 6-11* is/are rejected.

7)☒ Claim(s) *5* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *05 April 2001* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

The response filed February 28, 2003 (Paper No. 12) in response to the Office Action of November 20, 2002 is acknowledged and has been entered.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.

Drawings

In order to avoid abandonment, the drawing informalities noted on PTO-948 attached to Paper No. 8, mailed on September 6, 2002, must now be corrected. Correction can only be effected in the manner set forth in the above noted paper.

Claim Objections

The objection of claim 5 because of the following informalities **is maintained**: The claim is objected to because it is dependent on a rejected claim. SEQ ID NO: 1 is free of the prior art of record. Appropriate correction is requested.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

The rejection of claims 1-4 and 6-11 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter

which applicant regards as the invention **is maintained** for reasons of record. The claim is drawn to an isolated and purified nucleic acid molecule that encodes an "infectious" GBV-C. According to the specification (page 6, lines 8-20 and page 18-19) an "infectious nucleic acid" is defined as a full-length cDNAs or RNA transcript, which is **capable of yielding an infectious GBV-C particle** from an infected cell (page 19, lines 1-2). While an "isolated and purified" (paragraph spanning page 6-7) is defines as a nucleic acid molecule which is not part of an intact GBV-C virus. A cDNA clone made from the full-length or a less-than full-length transcript is also contemplated within the scope of the invention. The nucleic acid molecule encoding GBV-C may contain a contiguous nucleic acid sequence encoding one or more GBV-C genes and regulatory regions and be of the following lengths: 10-12000 nt. (see paragraph spanning page 20-21). The claim is not clear because it can be interpreted in two different ways:

(1) the claim can be interpreted to require full-length cDNA and RNA that is able to replicate *in vitro*; or

(2) the claim can be interpreted as being less than a full-length clone and requiring anywhere from 10-12000 nt.

Applicant's arguments are directed to the term "infectious" which is interpreted to be an intended use. The specification has not provided any information regarding the structural requirements necessary to make to make a GBV-C nucleotide sequence "infectious". The specification only indicates that the sequence be **capable of yielding** an infectious GBV-C particle from in infected cell. Neither the specification nor the declaration by Jack Stapleton M.D. have defined the structures which make the nucleic acid molecule infectious. The declaration merely indicates that the prior art did not test whether the nucleic is capable of being

infectious. If a prior art structure is capable of performing the intended use as recited in the preamble, then it meets the claim. See, e.g., *In re Schreiber*, 128 F.3d 1473, 1477, 44 USPQ2d 1429, 1431 (Fed. Cir. 1997). A patent applicant is free to recite features of an apparatus either structurally or functionally. See *In re Swinehart*, 439 F.2d 210, 212, 169 USPQ 226, 228 (CCPA 1971) (" [T]here is nothing intrinsically wrong with [defining something by what it does rather than what it is] in drafting patent claims."). Yet, choosing to define an element functionally, i.e. , by what it does, carries with it a risk. The court stated in *Swinehart*, 439 F.2d at 213, 169 USPQ at 228: where the Patent Office has reason to believe that a functional limitation asserted to be critical for establishing novelty in the claimed subject matter may, in fact, be an inherent characteristic of the prior art, it possesses the authority to require the applicant to prove that the subject matter shown to be in the prior art does not possess the characteristic relied on (*In re Schreiber*, 128 F.3d 1473, 1431, 44 USPQ2d 1429, 1431 (Fed. Cir. 1997)).

Therefore, it remains unclear what is being claimed by the instant invention.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The rejection of claim 1-4 and 6-11 under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an infectious full-length clone of GBV-C set out in SEQ ID NO:1, does not reasonably provide enablement for an infectious nucleic acid that is less-than or greater-than the full-length clone is maintained for reasons of record. Applicant's arguments

are that some experimentation is permissible and that the cited art is non-analogues to the claimed subject matter.

In response to applicant's argument that *Pang et al.* reference is nonanalogous art, because it does not specifically address problems with GBV-C and thereby would not be relevant for an enablement rejection. It has been held that a prior art reference must either be in the field of applicant's endeavor or, if not, then be reasonably pertinent to the particular problem with which the applicant was concerned, in order to be relied upon as a basis for rejection of the claimed invention. See *In re Oetiker*, 977 F.2d 1443, 24 USPQ2d 1443 (Fed. Cir. 1992). In this case, *Pang et al.* utilize a flavivirus construct (note GBV-C is also a flavivirus) although the authors goal may not have been to construct an infectious construct the reference does not have to have the same goal as the claimed invention. The reference clearly shows that a virus construct from the same family of viruses, will allow for the replication of the heterologous nucleic acid but they do not produce particles and are thereby not infectious. The reference clearly indicates that more is required in order to produce an infectious nucleic acid. Neither the art nor the instant specification have provided any guidance as to the structural requirements of the nucleic acid that are necessary to produce an infectious particle.

The Office agrees that some experimentation is permissible, however, it the degree of uncertainty and predictability that determines whether the claimed subject matter falls outside the predictability in the art requiring undue experimentation. The specification provides the following working example, they have shown that the cell culture supernatant from a full-length infectious GBV-C clone (SEQ ID NO:1) contains infectious virus. This was determined by incubating the supernatant with new uninfected cells (see example 4) and observing signs of

infection. The description of a single example which utilizes the full-length clone does not provide sufficient guidance to make infectious clones that may be smaller or larger in size. The specification has not provided any information regarding the structural requirements necessary to make to make a GBV-C nucleotide sequence infectious. Therefore, without specific guidance or direction and /or working examples, one of ordinary skill in the art would not be able to reproducibly practice the entire scope of the invention as claimed, without undue experimentation.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for the purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

The rejection of claims 1-4, 6, 7 and 9-10 under 35 U.S.C. 102(b) as being anticipated by Kim et al. (U.S. Pat. No. 5,856,134, see IDS) **is maintained** for reasons of record. Applicant's arguments and declaration have been fully considered but they fail to persuade. Applicant's arguments are that the reference does not show an infectious clone because it did not test the nucleic acid sequences.

Kim et al. disclose the entire coding region of two hepatitis-G virus DNA clones which are 9.4 kilobases in size (see SEQ ID NOs: 14 and 182). Genomic RNA was extracted (isolated and purified) from purified virions (see column 54, lines 40-52). The reference further discloses the expression and purification of HGV virus protein using a GST fusion construct with a pGEX vector in *E. coli.* (see Example 7), the plasmid contains a heterologous nucleic acid sequence and a promoter for the expression of the construct in a prokaryotic host.

If a prior art structure is **capable** of performing the intended use as recited in the claim, then it meets the claim. See, e.g., *In re Schreiber*, 128 F.3d 1473, 1477, 44 USPQ2d 1429, 1431 (Fed. Cir. 1997). A patent applicant is free to recite features of an apparatus either structurally or functionally. See *In re Swinehart*, 439 F.2d 210, 212, 169 USPQ 226, 228 (CCPA 1971) (" [T]here is nothing intrinsically wrong with [defining something by what it does rather than what it is] in drafting patent claims."). Yet, choosing to define an element functionally, i.e., by what it does, carries with it a risk. The court stated in *Swinehart*, 439 F.2d at 213, 169 USPQ at 228: where the Patent Office has reason to believe that a functional limitation asserted to be critical for establishing novelty in the claimed subject matter may, in fact, be an inherent characteristic of the prior art, it possesses the authority to require the applicant to prove that the subject matter shown to be in the prior art does not possess the characteristic relied on (*In re Schreiber*, 128 F.3d 1473, 1431, 44 USPQ2d 1429, 1431 (Fed. Cir. 1997)).

Applicants have not pointed to the structural differences that are required to distinguish the claimed invention over the cited prior art, therefore, the instant rejection is maintained.

The rejection of claims 1 and 2 under 35 U.S.C. 102(b) as being anticipated by Xiang et al. (Journal of Virology, 1998, see IDS) **is maintained** for reasons of record. Applicant's arguments and declaration have been fully considered but they fail to persuade. Applicant's arguments are that the reference does not show an infectious clone because it did not test the nucleic acid sequences.

Xiang et al. disclose RNA extraction (isolation and purification) of HGV RNA from patient plasma samples (see figure 1, and materials and methods).

If a prior art structure is **capable** of performing the intended use as recited in the claim, then it meets the claim. See, e.g., *In re Schreiber*, 128 F.3d 1473, 1477, 44 USPQ2d 1429, 1431 (Fed. Cir. 1997). A patent applicant is free to recite features of an apparatus either structurally or functionally. See *In re Swinehart*, 439 F.2d 210, 212, 169 USPQ 226, 228 (CCPA 1971) (" [T]here is nothing intrinsically wrong with [defining something by what it does rather than what it is] in drafting patent claims."). Yet, choosing to define an element functionally, i.e. , by what it does, carries with it a risk. The court stated in *Swinehart*, 439 F.2d at 213, 169 USPQ at 228: where the Patent Office has reason to believe that a functional limitation asserted to be critical for establishing novelty in the claimed subject matter may, in fact, be an inherent characteristic of the prior art, it possesses the authority to require the applicant to prove that the subject matter shown to be in the prior art does not possess the characteristic relied on (*In re Schreiber*, 128 F.3d 1473, 1431, 44 USPQ2d 1429, 1431 (Fed. Cir. 1997)).

Applicants have not pointed to the structural differences that are required to distinguish the claimed invention over the cited prior art, therefore, the instant rejection is maintained.

The rejection of claims 1-3, 6 and 9-11 under 35 U.S.C. 102(e) as being anticipated by Pilot-Matias et al. (U.S.Pat. No. 6,156,495) **is maintained** for reasons of record. Applicant's arguments and declaration have been fully considered but they fail to persuade. Applicants arguments are that the reference does not show an infectious clone because it did not test the nucleic acid sequences.

Pilot-Matias et al. discloses the production of fusion proteins comprising HGBV virus sequences, the nucleic acids encoding the HGBV virus sequences are inserted into a pSFV1 construct, which contains the heterologous promoter Sp6. The plasmids are linearized before *in vitro* RNA synthesis is performed (see column 45, lines 5-62, and table 5). Therefore, the instant invention is anticipated by Pilot-Matias et al.

If a prior art structure is **capable** of performing the intended use as recited in the claim, then it meets the claim. See, e.g., *In re Schreiber*, 128 F.3d 1473, 1477, 44 USPQ2d 1429, 1431 (Fed. Cir. 1997). A patent applicant is free to recite features of an apparatus either structurally or functionally. See *In re Swinehart*, 439 F.2d 210, 212, 169 USPQ 226, 228 (CCPA 1971) (" [T]here is nothing intrinsically wrong with [defining something by what it does rather than what it is] in drafting patent claims."). Yet, choosing to define an element functionally, i.e. , by what it does, carries with it a risk. The court stated in *Swinehart*, 439 F.2d at 213; 169 USPQ at 228:

where the Patent Office has reason to believe that a functional limitation asserted to be critical for establishing novelty in the claimed subject matter may, in fact, be an inherent characteristic of the prior art, it possesses the authority to require the applicant to prove that the subject matter shown to be in the prior art does not possess the characteristic relied on (*In re Schreiber*, 128 F.3d 1473, 1431, 44 USPQ2d 1429, 1431 (Fed. Cir. 1997)).

Applicants have not pointed to the structural differences that are required to distinguish the claimed invention over the cited prior art, therefore, the instant rejection is maintained.

Conclusion

Claims 1-4 and 6-11 are rejected.

Claim 5 is objected to.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ulrike Winkler, Ph.D. whose telephone number is 703-308-8294. The examiner can normally be reached M-F, 8:30 am - 5 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel, can be reached at 703-308-4027.

The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for informal communications use 703-308-4426.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Ulrike Winkler, Ph.D.

JAMES HOUSEL 6/16/03
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600